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April 15, 2013

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Generic Name: 1-alkyl-2-(heteromonocyclic-heteromonocyclic)-hydrazine derivative

This letter is to inform you of the results of multiple toxicity studies with the above referenced R&D test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

Rat Pharmacokinetics Screen
A single oral gavage dose at 25 mg/kg bw was given to 3 rats/sex. Blood was collected at predose, 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144, and 168 hours for analysis of the parent chemical in plasma. Clinical signs were checked at 2, 4, 24, 48, 72, 96, 120, 144, and 168 hrs. One male rat was found dead at 96 hr. and one female rat was sacrificed in extremis at 102 hr. Following clinical signs were noted at or after 72 hours: lethargy, decreased muscle tone, ataxia, rapid breathing, spasms, high or low carriage (posture), , abnormal gait (dragging hind end), prostrate, splayed limbs (hind limbs), , no righting reflex, wet fur underbody, cold to the touch, and vocalization, The female rat sacrificed in extremis had signs of chromodacryorrhea periocular .

Chromosome Aberrations *In Vitro*
The test substance was evaluated for its ability to induce chromosome aberrations *in vitro* in human peripheral blood lymphocytes (HPBL) in the absence and presence of an exogenous metabolic activation system (Aroclor-induced rat liver S9). HPBL cells were treated for 22 hours in the non-activated test system and for 4 hours in the S9 activated test system. The cells were harvested 22 hours after initiation of the treatment. The cells were exposed to twelve concentrations of the test substance ranging from 1 to 2870 µg/mL (10 mM), as well as a vehicle and positive control. A visible precipitate was observed in the treatment medium at concentrations ≥ 2000 µg/mL in both test conditions. The top concentration for cytogenetic analysis in the 22-hour non-activated test condition was 750 µg/mL, which caused a 54.7% mitotic inhibition relative to the negative control. The top concentration for cytogenetic analysis in the 4-hour S9-activated test condition was 1000 µg/mL, which caused a 70.6% mitotic inhibition relative to the negative control. The percentage of cells with structural aberrations in the test substance-treated groups was significantly increased above the negative control in a dose-dependent trend in the 22-hour non-activated test condition. The response was greater than that noted with concurrent positive control.

Oral Approximate Lethal Dose Screen
The test substance was administered by oral gavage to one fasted female rat at a dose of 300, 1000, or 2000 mg/kg and to one fasted male rat at a dose of 2000 mg/kg. The rats were observed for mortality, clinical signs, and body weight effects for up to 14 days after dosing. Death occurred in all rats except for the female rat dosed at 1000 mg/kg. The clinical signs observed included dragging of hind legs, ataxia, hypoactivity, and prone posture. The approximate lethal dose of the test substance was 300 mg/kg in female rats and was 2000 mg/kg in male rats, the only dose tested in males.

Sincerely,

Company Sanitized

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

   [ ]

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   [ ]

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

   [ ]

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

   [ ]

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

   [ ]

6. Does the information claimed as confidential appear or is it referred to in any of the following:

   a. Advertising or promotional material for the chemical substance or the resulting and product[ ]

   b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this

information as it appears when accompanying the substance and/or product at the time of transfer or sale); [ ]

c. Professional or trade publications; or
[ ]

d. Any other media or publications available to the public or to your competitors.
[ ]

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

[ ]

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.

[ ]

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

[ ]

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market? [ ]

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
[ ]

b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

[ ]

c. What is the substance used for and what type of product(s) does it appear in.

[ ]

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

[ ]

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. confidential processes used in manufacturing the substance; [ ]

b. if a mixture, the actual portions of the substance in the mixture; [ ]

c. information unrelated to the effects of the substance on human health or the environment? [ ]

If your answer to any of the above questions is yes, explain how such information would be revealed.

13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

[ ]

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

[ ]